c.) Remarks

The claims have been amended for better idiomatic usage or so as to recite the present invention with the specificity required by statute. Additionally, claims 8 and 12 have been cancelled as superfluous and new claims 18 and 19 are presented in order to more specifically recite various preferred embodiments of the present invention. No new matter has been added.

Claims 1-17 stand rejected under 35 U.S.C §102(b) as anticipated by U.S. Patent No. 4,047,866 to Shah and U.S. Patent No. 3,461,195 to Sebastiani. Claims 1-17 also stand rejected under 35 U.S.C. §103(a) as being obvious over Shah or Sebastiani.

In the Office Action, the Examiner kindly suggests amending the claims, in order to overcome the prior art rejection, (1) by adding additional method steps to the instant claims that differentiate it from the prior art or (2) by reciting the specific drugs with which this new method is successful. If the latter, the Examiner also suggests that Applicants provide comparative scientific evidence that the prior art method would not be successful with the drugs contemplated for use herein.

In order to reduce the issues and avoid the need for conducting comparative experiments, Applicants have proceeded according to the first manner suggested by the Examiner. In this regard, the Examiner's assistance and cooperation in expediting the allowance of this application is gratefully acknowledged.

As the Examiner will appreciate, the amended claims relate more specifically to a method of producing compressed tablets (claims 1-7, 9 and 15) and a compressed tablet (claims 10, 11, 13, 14 and 18) in which an active compound which is

readily denaturalized or inactivated (or of which elution is delayed) when compressed at a pressure greater than 1 ton/cm^2 can be included.

In particular, the pending claims recite explicitly the features by which this has been achieved, namely by (i) providing the active compound as a dispersion in a powdered or granular material, by (ii) applying to punch and die surfaces a tabletting lubricant admixed with pulsating vibration air, and (iii) not providing said tabletting lubricant within the molding material while (iv) nevertheless ensuring that sufficient tabletting lubricant is utilized, e.g., from 0.0001 to 0.2 weight percent.

These features --let alone these combination of features-- are neither taught nor suggested by the prior art.

At the outset, it should be noted for the record that the present invention is not at all a prior art internal lubrication method (e.g., tabletting by compressing a molding material containing a lubricant) simply modified by placing the lubricant elsewhere. That is, the present invention enables production of pressed tablets particularly using active compounds that were previously considered impossible to be compressed.

Shah discloses an automatic self lubricating type rotary tabletting machine. According to the Examiner, Shah teaches controlling the amount of lubricant sprayed on the punches and dies. The Examiner also states that Sebastiani teaches spraying a lubricant on the punch of the single station tabletting machine and lubricating apparatus therefor.

However, Applicants' detailed review shows that neither reference employs a lubricant admixed with pulsating vibration air, nor does either reference contemplate an active material that is denaturalized or inactivated when tabletted at high pressure, let alone

selecting and dispersing the same in a powder or granule. Accordingly, the foregoing claims are amended to explicitly recite these features. For at least these reasons, Applicants respectfully submit the prior art fails to make out a *prima facie* case of anticipation or obviousness as to the amended claims.

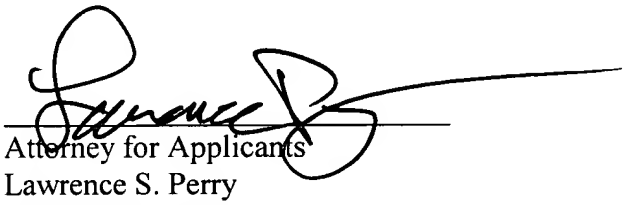
Moreover, Applicants' dependent claims recite patentable subject matter in their own right. For instance, claims 5 and 19 specify that the tabletting lubricant (which is not contained within the tablet) in stearate acid metal salt. Similarly, claims 15 and 18 specify the hardness of the tablet, which was not heretofore obtainable using powder or granulated materials compressed below 1 ton/cm^2.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-7, 9-11, 13-15, 18 and 19 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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Amendments in a Revised Format Now Permitted

Office of Patent Legal Administration << Pre-OG Notices << *<< Amendments in a Revised Format Now Permitted*

The United States Patent and Trademark Office (USPTO or Office) is permitting applicants to submit amendments in a revised format as set forth herein. The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

The revised amendment format is an expansion of the special amendment process instituted for a prototype Electronic File Wrapper program described in USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING, 1265 Off. Gaz. Pat. Office 87 (Dec. 17, 2002) ("Prototype Announcement"). The special amendment process (which was limited to claims) has proven overwhelmingly acceptable to applicants participating in the prototype and beneficial to examiners. The revised amendment format provides for amendments to be made to the specification and the drawings in addition to the claims.

Effective immediately, **all** applicants, including applicants participating in the prototype, may submit amendments using the revised amendment format set forth herein. Applicants may wish to submit all amendments in the revised amendment format because: (1) it will facilitate transition to a revised amendment format when it becomes mandatory, (2) inconsistent versions of claim amendments (clean and marked-up) will be avoided, and (3) time and resources will be saved.

WAIVER of 37 CFR 1.121

The provisions of 37 CFR 1.121(a), (b), (c) and (d) are waived for amendments to the **claims, specification, and drawings** in all applications in all Technology Centers where the amendments comply with the revised amendment format detailed below. Note: The revised amendment format (and the waiver) does **not** apply to 37 CFR 1.121(h) and (i) which indicate that amendments to reissue applications and reexamination proceedings are governed by 37 CFR 1.173 for reissue applications and 37 CFR 1.530 (d)-(k) for *ex parte* and *inter partes* reexaminations.

In addition, the WAIVER indicated in the above mentioned Prototype Announcement for the limited (claims only) amendment process of that prototype is also expressly continued and amendments in applications (other than reissue applications) in all Technology Centers that comply with the requirements in that announcement will be acceptable.

REVISED AMENDMENT FORMAT

I. Begin Sections on Separate Sheets:
Each section of an amendment paper (e.g., Amendments to the Specification, Amendments to the Claims, Remarks) shall begin on a separate sheet to facilitate separate indexing and electronic scanning of the document.

For example, each of the following four sections of an amendment paper must start on a separate sheet:

a.) Introductory Comments

b.) Amendments to the Specification
c.) Amendments to the Claims
d.) Remarks

II. Submit Only One Version (with markings) of an Amended Part:
The requirement to provide two versions of a replacement paragraph, section, or claim (a clean version and a marked up version), as set forth in current 37 CFR 1.121, is waived where the format set forth below is followed.

III. Amendments to the Claims

A. A Complete Listing of Claims is Always Required:

If an amendment adds, changes or deletes any claim, a detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remains under examination in the application, must be presented, and the amendment to the claims is expressed in the listing. The listing shall be presented as follows:

1. Ascending Order and Status Identifier Required
The listing shall be provided in sequential ascending numerical order (beginning with claim 1). A status identifier shall be provided for every claim in a parenthetical expression following the claim number (e.g., "Claim 1. (original)"). A list of acceptable status identifiers is set forth in part B, below. The text of **all** claims under examination shall be submitted each time any claim is amended. Cancelled and withdrawn claims should be indicated by only the claim number and status. The text of cancelled or withdrawn claims should not be presented.

2. Markings in Currently Amended Claims Required
All claims *being currently amended* shall be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). No separate "clean" version should be submitted for currently amended claims, as this requirement has been eliminated. **Markings should only be made in claims being currently amended in an amendment paper**.

3. Only Clean Text Required for Other Claims Under Examination.
The text of pending claims *not being currently amended* that are under examination shall be presented in a clean version in the listing. Any claim presented in clean version constitutes an assertion that it has not been changed relative to the immediate prior version.

4. Status to Effect Claim Cancellation or Addition.
A claim may be cancelled by merely indicating the status of the claim as cancelled. Any new claim added by amendment must be indicated by the appropriate status identifier and shall not be underlined. Thus, added new claims of status (new), (reinstated - formerly claim #_) and (re-presented - formerly dependent claim #_) must be presented in clean version. Additional claims may be subject to additional fees, as appropriate.

5. When Grouping of Claims is Permitted.
Consecutive cancelled or withdrawn claims may be aggregated into one line of the listing (e.g. Claims 1 - 5 (cancelled)).

6. Use "Currently Amended" Status Where Applicable.
If any "previously reinstated" or "previously re-presented" claim is being amended, the status shall be indicated as "currently amended" with markings as indicated in paragraph A2, above. Multiple status identifiers should not be used for any single claim.

B. Status Identifiers that May be Used:

In order to promote uniformity and consistency, only the following eleven (11) defined status identifiers should be used to indicate the status of the claims (in parentheses after the claim number):

1. (Original):	Claim filed with the application following the specification (i.e., not added by preliminary amendment).
2. (Currently amended):	Claim being amended in the current amendment paper.
3. (Previously amended):	Claim not being currently amended, but which was amended in a previous amendment paper.
4. (Cancelled):	Claim cancelled or deleted from the application.
5. (Withdrawn):	Claim still in the application, but in a non-elected status.
6. (Previously added):	Claim added in an earlier amendment paper.
7. (New):	Claim being added in the current amendment paper.
8. (Reinstated - formerly claim # _):	Claim deleted in an earlier amendment paper, but re-presented with a new claim number in current amendment.
9. (Previously reinstated):	Claim deleted in an earlier amendment and reinstated in an earlier amendment paper.
10. (Re-presented - formerly dependent claim # _):	Dependent claim re-presented in independent form in current amendment paper.
11. (Previously re-presented):	Dependent claim re-presented in independent form in an earlier amendment, but not currently amended.

C. Example of Listing of Claims:

Claims 1-5 (cancelled)
Claim 6 (withdrawn)
Claim 7 (previously amended): A bucket with a handle.
Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.
Claim 9 (withdrawn)
Claim 10 (original): A bucket with a wooden handle.
Claim 11 (cancelled)

Claim 12 (new): A bucket with plastic sides and bottom.
Claim 13 (previously added): A bucket having a circumferential upper lip.
Claim 14 (re-presented - formerly claim 11): A black bucket with a wooden handle.

IV. Amendments to the Specification

Amendments to the specification are to be made by presenting replacement paragraphs, sections or a substitute specification marked up to show changes made relative to the immediate prior version, as set out in 37 CFR 1.121(b). The changes should be shown by strikethrough (for deleted matter) or underlining (for added matter). No accompanying "clean" version shall be supplied. The amendments to the specification shall be presented only one time, and will not appear in successive amendment documents.

V. Amendments to the Drawings

Amendments to the drawing figures shall be made by presenting replacement figures which include the desired changes, without markings, and which comply with § 1.84. The changes shall be explained in the accompanying remarks section of the amendment paper. If the amended drawings are not approved, the applicant will be notified in the next Office action. Any amended drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure number in the amended drawing should not be labeled as "amended."

For further information on the prototype image electronic processing of patent applications, please contact the Search and Information Resources Administration at: **image.processing@uspto.gov**. Any questions regarding the submission of amendments pursuant to the revised practice set forth in this notice should be directed to Elizabeth Dougherty (**Elizabeth.Dougherty@uspto.gov**), Gena Jones (**Eugenia.Jones@uspto.gov**) or Joe Narcavage (mailto:**Joseph.Narcavage@uspto.gov**). For information on the waiver or legal aspects of the program, please contact Jay Lucas (**Jay.Lucas@uspto.gov**) or Rob Clarke (**Robert.Clarke@uspto.gov**).

Date: 1/31/03

Signed: /s/
STEPHEN KUNIN
Deputy Commissioner for Patent
Examination Policy
